Exhibit H

SUPPLEMENTAL REPORT OF PEGGY PENCE, PhD, RAC, FRAPS
RE: TENSION FREE VAGINAL TAPE (TVT) SYSTEM
AND
MODIFIED GYNECARE TVT OBTURATOR SYSTEM
PRODUCT LIABILITY LITIGATIONS
vs. ETHICON, INC.
AND JOHNSON & JOHNSON
(Collectively referred to in this Report as Ethicon)

According to the "Updated IFU Index and Production Bates Range Chart" produced by Ethicon on November 6, 2015, there was one update to the TVT IFU (in use 12/9/14 through 8/31/15) and one update to the TVT-O IFU (in use 12/15/14 through 9/16/15)[25] since the time of my prior Reports regarding these products. Notably, there were no changes in those IFUs regarding the listing of adverse reactions as compared to IFUs in previous use. (Reference my TVT October 14, 2013, and June 12, 2014, Reports and July 17, 2014, and April 24, 2015 [First Supplemental] TVT-O Reports.) The safety information missing from prior IFUs, discussed in my prior Reports, persisted through the implementation of the 2015 revised IFUs for both products.

It is noteworthy that essentially all of the risk information that Health Canada requested Ethicon to add to the TVT and TVT-O IFUs was specified in my prior Reports (dating back to October 14, 2013, for my initial TVT Report) as safety information that was missing from the product IFUs. Of further note, TGA requested inclusion of all known complications identified in the clinical literature, risk assessment documentation, and post-market data, which were sources that I also evaluated to assess safety information missing from the product IFUs. Thus, both Health Canada's request and TGA's request for labeling changes provide corroboration from authoritative bodies of my prior opinions as regards missing safety information.

Additionally, Ethicon added a number of other adverse reactions or warnings that I had enumerated as missing safety information in my prior Reports to the revised IFUs implemented in 2015. Although these revised IFUs included much of the safety information specified as missing from IFUs in my prior Reports, my opinions remain the same as regards other labeling deficiencies or safety information that I previously specified as missing but which was not included in the 2015 revised IFUs.

V. ADVERSE MEDICAL DEVICE EVENT REPORTING: MAUDE DATABASE

Adverse event databases, such as the MAUDE Database, provide real world clinical experience that provide useful information about device safety and performance. This information should be considered as part of the ongoing clinical evaluation and risk analysis process for the life cycle of the device, and actions should be taken as appropriate to manage risk, e.g., updating safety information in the Instructions for Use. (Reference Exhibit 1, Section II.G.) Accordingly, Exhibit 2 provides a current overview of the results of MAUDE database searches for total number of medical device reports from 1999 through 2015 for Ethicon and a number of competitor surgical mesh devices marketed for the repair of SUI and POP. The significance of the large number of adverse event reports is highlighted by the industry-accepted recognition that there is vast underreporting of device-related problems, with estimates that as few as 1 in 100 medical device reportable events is actually reported. (Reference Exhibit 1, Section III.)

[25] In re: Ethicon, Inc. Pelvic Repair System, Products Liability Litigation, In re: Pelvic Mesh/Gynecare Litigation, Updated IFU Index and Production Bates Range Chart, Produced to Plaintiffs on 11/6/15 Pursuant to Protective Orders (Ethicon MDL No. 2327 and New Jersey Litigation, Case No. 291 CT).